

PACKAGE LEAFLET

Package leaflet: Information for the user

Gardette 160 micrograms/4.5 micrograms/inhalation, Inhalation Powder Budesonide/Formoterol fumarate dihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Gardette is and what it is used for
2. What you need to know before you use Gardette
3. How to use Gardette
4. Possible side effects
5. How to store Gardette
6. Contents of the pack and other information

1. What Gardette is and what it is used for

Gardette is an inhaler that is used to treat asthma in adults and adolescents aged 12-17 years. It is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older. It contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called 'long-acting beta₂ adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Asthma

Gardette can be prescribed for asthma in two different ways.

a) Some people are prescribed two asthma inhalers: Gardette and a separate 'reliever inhaler'.

- They use Gardette every day. This helps to prevent asthma symptoms from happening.
- They use their 'reliever inhaler' when they get asthma symptoms, to make it easier to breathe again.

b) Some people are prescribed Gardette as their only asthma inhaler.

- They use Gardette every day. This helps to prevent asthma symptoms from happening.
- They also use Gardette when they need extra doses for relief of asthma symptoms, to make it easier to breathe again and if agreed with the doctor also to prevent asthma symptoms from happening (for example, when exercising or on exposure to allergens). They do not need a separate inhaler for this.

Chronic obstructive pulmonary disease (COPD)

Gardette can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

2. What you need to know before you use Gardette

Do not use Gardette:

- if you are allergic to budesonide, formoterol or the other ingredient of this medicine (listed in section 6), which is lactose (which contains small amounts of milk protein).

Warnings and precautions

Talk to your doctor or pharmacist before using Gardette if:

- You are diabetic.
- You have a lung infection.
- You have high blood pressure or you have ever had a heart problem (including an uneven heartbeat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- You have low levels of potassium in your blood.
- You have severe liver problems.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Gardette

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eye drops (such as timolol for glaucoma).
- Medicines for a fast or uneven heart beat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as ‘water tablets’ (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines called ‘HIV-protease inhibitors’ (such as ritonavir) to treat HIV infection.
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- Medicines for Parkinson’s disease (such as leva-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Gardette.

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

Pregnancy, breast-feeding and fertility

- If you are pregnant, or planning to get pregnant, talk to your doctor before using Gardette - do not use Gardette unless your doctor tells you to.
- If you get pregnant while using Gardette, do not stop using Gardette but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using Gardette.

Driving and using machines

Gardette has no or negligible effect on your ability to drive or to use tools or machines.

Gardette contains lactose

Gardette contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use Gardette

- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- it is important to use Gardette every day, even if you have no asthma or COPD symptoms at the time.
- If you are using Gardette for asthma, your doctor will want to regularly check your symptoms.

If you have been taking steroid tablets for your asthma or COPD, your doctor may reduce the number of tablets that you take, once you start to use Gardette. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral steroid tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms. You should speak to your doctor if you are concerned as to whether you should continue to use Gardette.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Gardette, you should continue to use Gardette but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night with asthma.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.
- These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

Asthma

Gardette can be prescribed for asthma in two different ways. The amount of Gardette to use and when to use it depends on how it has been prescribed for you.

- If you have been prescribed Gardette and a separate reliever inhaler, read the section called 'a) Using Gardette and a separate reliever inhaler'.
- If you have been prescribed Gardette as your only inhaler, read the section called 'b) Using Gardette as your only asthma inhaler'.

a) Using Gardette and a separate reliever inhaler

Use your Gardette every day. This helps to prevent asthma symptoms from happening.

Adults (18 years and above)

- The usual dose is 1 or 2 inhalations, twice a day.
- Your doctor may increase this to 4 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Adolescents (12 to 17 years)

- The usual dose is 1 or 2 inhalations, twice a day.

- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.
- A lower strength of Gardette is available for children aged from 6 to 11 years.

Gardette is not recommended to be used in children who are younger than 6 years.

Your doctor (or asthma nurse) will help you to manage your asthma. They will adjust the dose of this medicine to the lowest dose that controls your asthma. However, do not adjust or stop the dose without talking to your doctor (or asthma nurse) first.

Use your separate ‘reliever inhaler’ to treat asthma symptoms when they happen. Always keep your ‘reliever inhaler’ with you to use when you need it. Do not use Gardette to treat asthma symptoms - use your reliever inhaler.

b) Using Gardette as your only asthma inhaler

Only use Gardette in this way if your doctor has told you to and if you are aged 12 or above.

Use your Gardette every day. This helps to prevent asthma symptoms from happening. You can take:

- 1 inhalation in the morning **and** 1 inhalation in the evening
- or**
- 2 inhalations in the morning
- or**
- 2 inhalations in the evening

Your doctor may increase this to 2 inhalations twice a day.

Also use Gardette as a ‘reliever inhaler’ to treat asthma symptoms when they happen and to prevent asthma symptoms from happening (for example, when exercising or on exposure to allergens).

- If you get asthma symptoms, take 1 inhalation and wait a few minutes.
- If you do not feel better, take another inhalation.
- Do not take more than 6 inhalations at a single time.

Always keep your Gardette Inhaler with you, so you can use it when you need it.

A total daily dose of more than 8 inhalations is not normally needed. However, your doctor may allow you to take up to 12 inhalations a day for a limited period.

If you regularly need to use 8 or more inhalations a day, make an appointment to see your doctor or nurse. They may need to change your treatment.

Do not use more than 12 inhalations in total in 24 hours.

If you are doing exercise and you get asthma symptoms, use Gardette as described here. It is important that you discuss with your doctor the use of Gardette to prevent asthma symptoms from happening; how often you exercise or how often you are exposed to allergens could impact the treatment that is prescribed to you.

Chronic Obstructive Pulmonary Disease (COPD)

- Only to be used by adults (aged 18 years and above).
- The usual dose is 2 inhalations twice a day.

Your doctor may also prescribe other bronchodilator drugs, for example anticholinergics (such as tiotropium or ipratropium bromide) for your COPD disease.

Preparing your new Gardette Inhaler

Before using your **new** Gardette Inhaler **for the first time**, you need to prepare it for use as follows:

- Unscrew the cover and lift it off. You may hear a rattling sound.
- Hold your Gardette Inhaler upright with the red grip at the bottom.
- Turn the red grip as far as it will go in one direction. Then turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should hear a click sound. It does not matter whether the click comes on the first or the second twist.
- Do this again, turning the red grip in both directions.
- Your Gardette Inhaler is now loaded and ready for use.

How to take an inhalation

Every time you need to take an inhalation, follow the instructions below.

1. Unscrew the cover and lift it off. You may hear a rattling sound.
2. **Hold your Gardette Inhaler upright** with the red grip at the bottom.



3. Do not hold the mouthpiece when you load your Gardette Inhaler. To load your Gardette Inhaler with a dose, turn the red grip as far as it will go in one direction.



Then turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should hear a click sound. It does not matter whether the click comes on the first or the second twist. Your Gardette Inhaler is now loaded and ready to use. Only load your Gardette Inhaler when you need to use it.

4. Hold your Gardette Inhaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through your Gardette Inhaler.
5. Place the mouthpiece gently between your teeth. Close your lips. Breathe in as deeply and as hard as you can through your mouth. Do not chew or bite on the mouthpiece.



6. **Remove your Gardette Inhaler from your mouth. Then breathe out gently.** The amount of medicine that is inhaled is very small. This means you may not be able to taste it after inhalation. If you have followed the instructions, you can still be confident that you have inhaled the dose and the medicine is now in your lungs.
7. If you are to take a second inhalation, repeat steps 2 to 6.
8. Replace the cover tightly after use.



9. Rinse your mouth with water after your daily morning and/or evening doses, and spit it out.

Do not try to remove or twist the mouthpiece. It is fixed to your Gardette Inhaler and must not be taken off. Do not use your Gardette Inhaler if it has been damaged or if the mouthpiece has come apart from your Gardette Inhaler.

As with all inhalers, caregivers should ensure that children prescribed Gardette use correct inhalation technique, as described above.

Cleaning your Gardette Inhaler

Wipe the outside of the mouthpiece once a week with a dry tissue. Do not use water or liquids.

When to start using a new inhaler

- The dose indicator tells you how many doses (inhalations) are left in your Gardette Inhaler starting with either 60 or 120 doses when it is full.



- The dose indicator is marked in intervals of 10 doses. Therefore, it does not show every dose.
- When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last 10 doses, the background of the dose indicator is red. When the '0' on the red background has reached the middle of the window, you must start using your new Gardette Inhaler.

Note:

- The grip will still twist and 'click' even when your Gardette Inhaler is empty.
- The sound that you hear as you shake your Gardette Inhaler is produced by a drying agent and not the medicine. Therefore, the sound does not tell you how much medicine is left in your Gardette Inhaler.
- If you load your Gardette Inhaler more than once by mistake before taking your dose, you will still only receive one dose. However, the dose indicator will register all the loaded doses.

If you use more Gardette than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

The most common symptoms that may occur after if you use more Gardette Turbuhaler than you should are trembling, headache or a rapid heartbeat.

If you forget to use Gardette

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do **not** take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If either of the following happens to you, stop using Gardette and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) or hives together with difficulties to breathe (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. If either of these symptoms occur, stop using your Gardette straightaway and use your 'reliever' inhaler.

Contact your doctor immediately as you may need to have your treatment changed. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Gardette.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Gardette Inhaler.
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking Gardette, they could be symptoms of a lung infection:

- Fever or chills.
- Increased mucus production, change in mucus colour.
- Increased cough or increased breathing difficulties.

Uncommon (may affect up to 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heartbeat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Gardette stop using Gardette and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heartbeat.

Very rare (may affect up to 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- changes in bone mineral density (thinning of the bones).
- cataract (clouding of the lens in the eye).
- glaucoma (increased pressure in the eye).
- a slowing of the rate of growth of children and adolescents.
- an effect on the adrenal gland (a small gland next to the kidney).

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Gardette

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or on the label of your inhaler after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gardette contains

The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 160 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate.

The other ingredient is lactose monohydrate (which contains milk proteins).

What Gardette looks like and contents of the pack

Gardette is an inhaler containing your medicine. The inhalation powder is white in colour. Each inhaler contains either 60 or 120 doses and has a white body with a red turning grip. The turning grip contains a Braille code with the number 6 for identification, to differ from other AstraZeneca inhaled products.

Gardette is available in packs of 1, 2, 3, 10 or 18 inhaler(s) containing 60 (or 120) doses.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Trade name and strength
Italy	Assieme 160 µg/4.5 µg/inhalation
Portugal	Assieme Turbohaler 160 µg/4.5 µg/inhalation
Spain	Rilast Turbuhaler 160 µg/4.5 µg/inhalation
Sweden	Gardette 160 µg/4.5 µg/inhalation

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